



July 22, 2021

NovaVision, Inc.
Navroze S. Mehta
President and CEO
3701 Fau Boulevard
Suite 210
Boca Raton, Florida 33431

Re: K023623

Trade/Device Name: NovaVision, Model 2.0
Regulation Number: 21 CFR 886.1605
Regulation Name: Perimeter
Regulatory Class: Class I
Product Code: HPT

Dear Navroze S. Mehta:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 22, 2003. Specifically, FDA is updating this SE Letter as an administrative correction corresponding to the correct classification regulation number, regulation name, regulatory class, and product code.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Elvin Ng, OHT1: Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices, (240) 402-4662, Elvin.Ng@fda.hhs.gov.

Sincerely,

 Charles Chiang -S

for Elvin Ng
Assistant Director
Retinal and Diagnostic Devices Team
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT
and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2003

Mr. Navroze S. Mehta
President and CEO
NovaVision Inc.
3701 Fau Boulevard
Suite 210
Boca Raton, Florida 33431

Re: K023623

Trade/Device Name: NovaVision Model 2.0
Regulation Number: Unclassified
Regulation Name: Attention Task Performance Recorder
Regulatory Class: Unclassified
Product Code: LQD
Dated: February 13, 2003
Received: February 19, 2003

Dear Mr. Mehta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

III. Indications for Use Statement

Applicant: NovaVision, Inc.

510(k) Number (if known): K023623

Device Name: NovaVision™

Indications For Use: NovaVision™ is intended for the diagnosis and improvement of visual functions in patients with impaired vision that may result from trauma, stroke, inflammation, surgical removal of brain tumors or brain surgery, and may also be used to improve visual function in patients with amblyopia.

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023623

APR 22 2003

K023623

X. 510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. § 807.92.

510(k) Submitter	NovaVision, Inc. Reservoir Place, Suite 205 1601 Trapelo Road Waltham, MA 02451
	<u>Contact:</u> Bernhard A. Sabel, Ph.D. Tel: +49-391-611 7100 Fax: +49-391-611 7103
Date summary was prepared	October 25, 2002
Trade Name	NovaVision™
Common Name	Attention Task Performance Recorder
Classification Name	Recorder, attention task performance
Product code	LQD
Predicate Devices	DynaVision 2000 (K911938) AA-1 System for the Treatment of Amblyopia (K012530)
Description	NovaVision™ consists of two computer software programs: (1) one intended for health care professionals – for the precise diagnosis of patients' visual deficiencies, the development of patient-specific therapy programs, and the analysis of results of patient therapy (NovaVision™ Diagnosis Software and Training Program); and (2) one intended for patients – therapeutic software for use by patients in their homes to train and improve impaired visual functions (NovaVision™-Therapy).
Intended Use	NovaVision™ is intended for the diagnosis and improvement of visual functions in patients with impaired vision that may result from trauma, stroke, inflammation, surgical removal of brain tumors or brain surgery, and may also be used to improve visual function in patients with amblyopia.

Comparison of technological characteristics to predicate device

NovaVision™ is substantially equivalent to the DynaVision 2000. These systems have the same intended use/indications, target population, and functionality, *i.e.*, the diagnosis and improvement of visual functions in patients with impaired vision by repetitively

presenting visual stimuli. NovaVision™ consists of different technology than the Dynavision 2000, but these differences do not raise new questions of safety and effectiveness, and NovaVision™ has been demonstrated to be as safe and effective as the Dynavision 2000.

NovaVision™ presents visual stimuli on a computer screen, while the Dynavision 2000 presents visual stimuli on a large light board. Further, NovaVision™'s computerization of visual stimuli makes it possible for patients to train at home.

NovaVision™ is also substantially equivalent to the AA-1 System for the Treatment of Amblyopia, a device consisting of software and accessories that is intended to treat amblyopia in patients nine years or older. Both devices consist of software that (1) collects and interprets diagnostic information concerning the extent of visual deficits in the form of patient responses to visual diagnostic tests; (2) reports diagnostic information useful for further diagnosis or treatment; and (3) presents visual training tasks individualized to each patient's specific diagnosis.

Clinical performance data and support of substantial equivalence determination

Two clinical studies have confirmed the effectiveness and reliability of NovaVision™ Diagnosis Software and Training Program in diagnosing patients' visual deficiencies, and five clinical studies have confirmed the safety and effectiveness of patient use of NovaVision™-Therapy to improve visual functions. Moreover, reference to a third-party clinical study strongly correlates with the capabilities of NovaVision™-Therapy to improve the vision of patients with amblyopia.